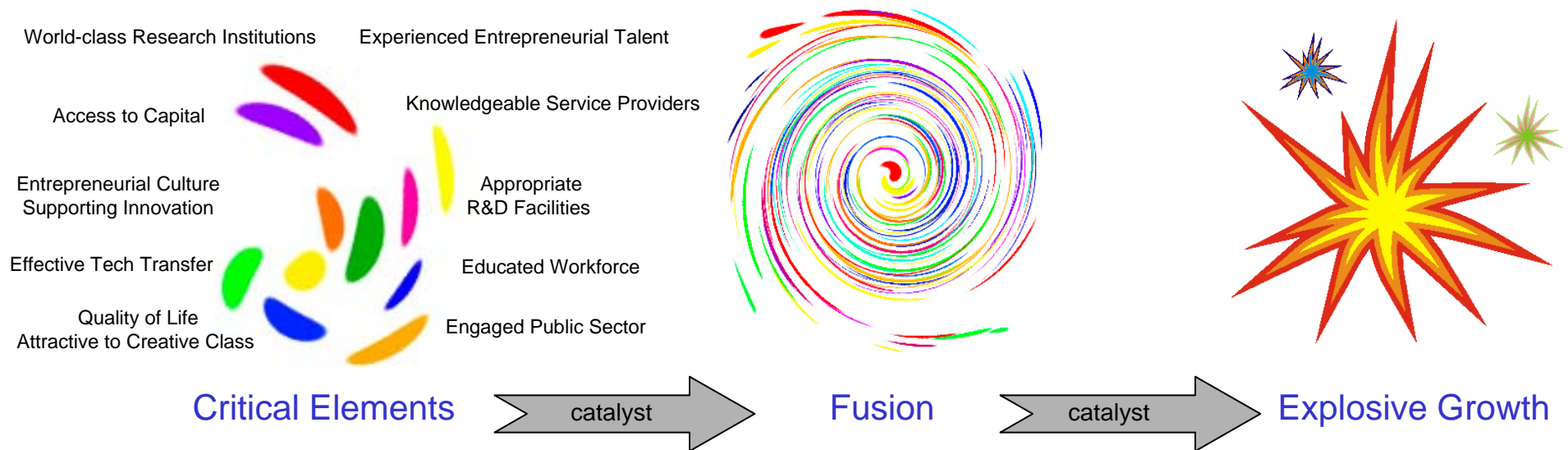


# Commercialization of University IP: Translational Research in BME Leading to Company Formation

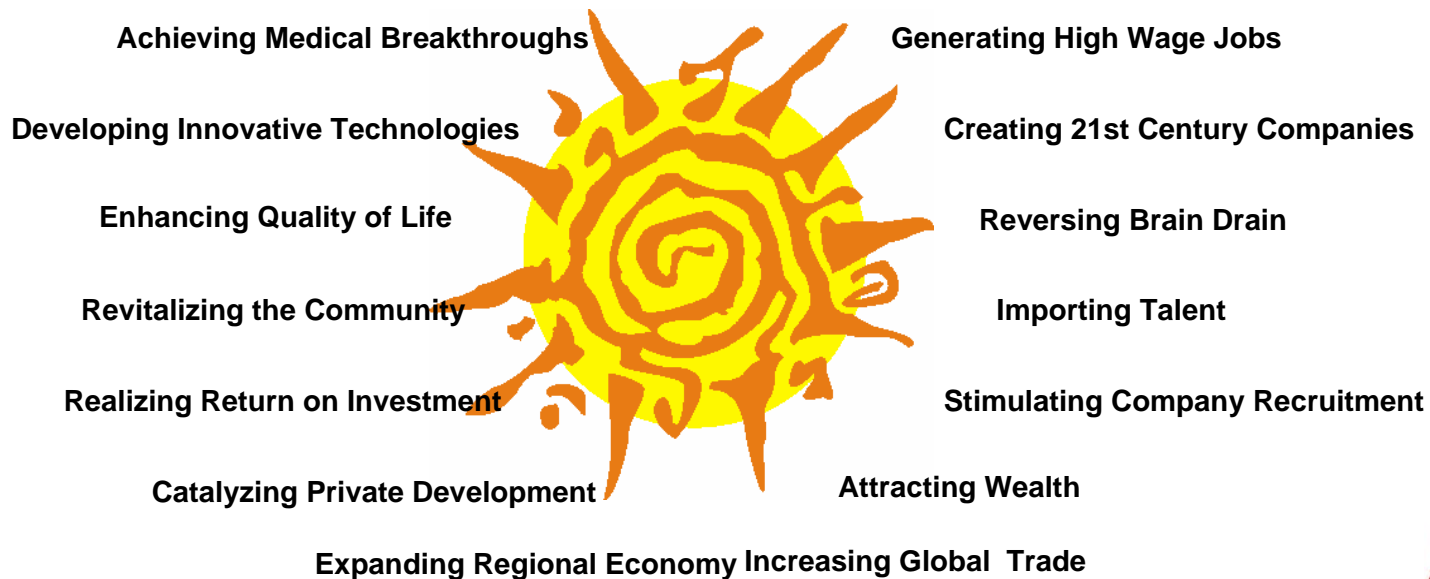
Marcia Mellitz  
President  
Center for Emerging Technologies



# Fusion of Critical Elements Generates Economic Vitality



## Transformation to Sustainable Economic Vitality



# Essential elements for growing your own companies

- 1) World-class Research Institutions
- 2) Effective Tech Transfer
- 3) Access to Capital
- 4) Appropriate R&D Facilities
- 5) Experienced Entrepreneurial Talent
- 6) Educated Workforce
- 7) Knowledgeable Service Providers
- 8) Entrepreneurial Culture Supporting Innovation
- 9) Engaged Public Sector
- 10) Quality of Life Attractive to Creative Class



# **Stage of company development determines necessary resources and services**

- Invention Phase
- Company Creation Phase
- Company Development Phase
- High Growth Phase
- Established Company Phase



# Life Science Value Chain Analysis

Essential Elements	Invention Phase	Company Creation Phase	Company Development Phase	High Growth Phase	Established Company Phase
1) World-class Research Institutions	On Target	Deficiencies	Deficiencies	Deficiencies	On Target
2) Effective Tech Transfer	Deficiencies	Deficiencies	Deficiencies	Deficiencies	Deficiencies
3) Access to capital	Deficiencies	Deficiencies	Deficiencies	Crisis	Deficiencies
4) Appropriate R&D Facilities	Deficiencies	Deficiencies	Deficiencies	Deficiencies	Deficiencies
5) Experienced Entrepreneurial Talent	Deficiencies	Deficiencies	Deficiencies	Crisis	Deficiencies
6) Educated Workforce	Deficiencies	On Target	Deficiencies	Crisis	Deficiencies
7) Knowledgeable Service Providers	On Target	On Target	On Target	On Target	On Target
8) Entrepreneurial Culture Supporting innovation	Deficiencies	Deficiencies	Deficiencies	Deficiencies	Deficiencies
9) Engaged Public Sector	Crisis	Crisis	Crisis	Crisis	Deficiencies
10) Quality of Life Attractive to Creative Class	Deficiencies	Deficiencies	Deficiencies	Deficiencies	Deficiencies

Key:

On Target

Deficiencies

Major Deficiencies

Crisis



# Life Science Value Chain Analysis

Essential Elements	Invention Phase	Company Creation Phase	Company Development Phase	High Growth Phase	Established Company Phase
1) World-class Research Institutions					
2) Effective Tech Transfer					
3) Access to Capital					
4) Appropriate R&D Facilities					
5) Experienced Entrepreneurial Talent					
6) Educated Workforce					
7) Knowledgeable Service Providers					
8) Entrepreneurial Culture Supporting Innovation					
9) Engaged Public Sector					
10) Quality of Life Attractive to Creative Class					

Key:

On Target

Deficiencies

Major Deficiencies

Crisis



# Benefits for the region - Direct

- Generating high wage jobs
- Creating 21<sup>st</sup> Century companies
- Stimulating company recruitment
- Attracting wealth
- Developing innovative technologies
- Catalyzing private development
- Expanding regional economy



# Benefits for the region - Indirect

- Reversing brain drain
- Importing talent
- Increasing global trade
- Achieving medical breakthroughs
- Enhancing quality of life
- Revitalizing the community
- Realizing return on investment





# Importance of Creating New Companies From University IP

- Create greater value for larger company acquisition by qualifying and de-risking the technology
- Accelerate the development process by providing a more flexible, innovative and efficient environment
- Save development costs by eliminating non-productive (efficacy) or problem (toxicity) approaches early on
- Enhance discoveries through translational and clinical research by experienced investigators
- Move technology from lab to potential commercialization



# Funding R&D to Reduce Technical Risk

- Translational research or proof of concept within the university environment (NIH, corporate, internal or external commercialization fund) - BioGenerator
- New company created (SBIRs, angel investors, seed and early-stage venture funds, federal and corporate grants, state subsidies, licenses, service contracts, university collaborations) - BioGenerator
- Clinical trials and commercialization (venture funds, IPO/private equity, joint ventures/partnering, state subsidies, federal grants, licensing, contracting out)



# **Role of incubators and research parks in technology commercialization**

1. Facilitate tech transfer, company formation, company-university, and company-company collaborations
2. Stimulate establishment of critical elements
3. Develop affordable specialized facilities
4. Support business and technology development
5. Assist companies in obtaining sources of funding
6. Foster creation of regional technology industry clusters



# Benefits for Universities

- Opportunities for entrepreneurial faculty to start or consult with companies
- Investigators' satisfaction from impact of new discoveries on people's lives
- Internships and career opportunities for students
- Funding for sponsored research
- Collaborators in grant applications
- Outlet for publicly funded research to benefit society
- Access to state-of-the-art equipment
- Stimulation of new ideas for research
- Sources of adjunct faculty



# Summary of Issues

## Universities

- Mission of universities is basic not applied or translational research
- Little public or private funding for proof of concept or prototype
  - o NCI and others are redirecting some grant dollars to translational research but total NIH funding is becoming more limited
  - o Few places have internal or community funds for translational grants to faculty
  - o More faculty interest in SBIR and STTR grants
- Reluctance of TT offices to do start-ups and unrealistic expectations
- Concerns over liability and conflicts of interest and commitment



# Summary of Issues

## Big Pharma

- Major drugs are coming off patent and little R&D is dedicated to developing significant new advancements
- Traditional model is based on producing and marketing block busters
- University discoveries are too numerous and too unproven to be useful for large companies – prefer to acquire technologies developed by a small company through Phase 2A, but provide limited funding to support development
- See biologics as a growth area but are not geared to do targeted marketing to limited populations



# Summary of Issues

## Commercialization

- Difficult to obtain funding, experienced entrepreneurs and affordable space for new start-ups
- Difficult and time consuming for faculty to license their own technology to create a company
- Conflict of interest limitations on funding additional research in the university lab
- Hard to raise angel and venture capital outside California and the North East



# Summary of Issues

## Government

- New and changing FDA requirements: orphan drugs, using biomarkers for an end point, differentiating targeted populations for clinical trials, genetic testing kits, continued patient tracking
- Tax incentives designed for larger, traditional companies
- Miss-information and fear of new technologies (Stem cells, pharmaceuticals from plants, genetically engineered crops)
- Politics-driven funding programs (bioterrorism, breast cancer)





# Summary of Issues

## Community and private sector

- Limited small bio-production facilities for clinical trials and regulatory expertise to get companies through clinical trials and FDA approvals
- Workforce is critical, particularly for management and highly technical positions
- Incubators and research parks are often not well planned or effectively managed
- Lack of knowledge and understanding among business and political leadership can be problematic
- New types of foundations are being created by individuals to fund translational research



# Value Created by CET 1998 - 2006

## Investment



City - \$2.2 M



State - \$6.3 M



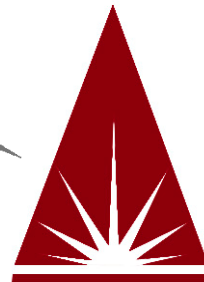
Fed - \$7.1 M



UMSL - \$1 M



Private - \$10.5 M (Incl. \$4.4 M debt)



\$27.1 M  
Invested in CET

Resulted in \$719 M  
of Attracted Capital  
&

\$1 B in Economic Impact

## Direct Results



Companies - 25



Jobs - 300

Payroll - \$117 M



Attracted Capital - \$719 M



## Economic Impact

Construction Jobs - 75



Indirect Jobs - 735



State & Local Taxes - \$66.8 M

Economic Impact - \$1 B





# CORTEX

(Center Of Research, Technology and Entrepreneurial eXchange)  
A Life Science Research and Development District

CORTEX East and West Development Districts



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